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Pesticide Fact Sheet Number 36: Chlorothalonil

(U.S.) Environmental Protection Agency
Washington, DC

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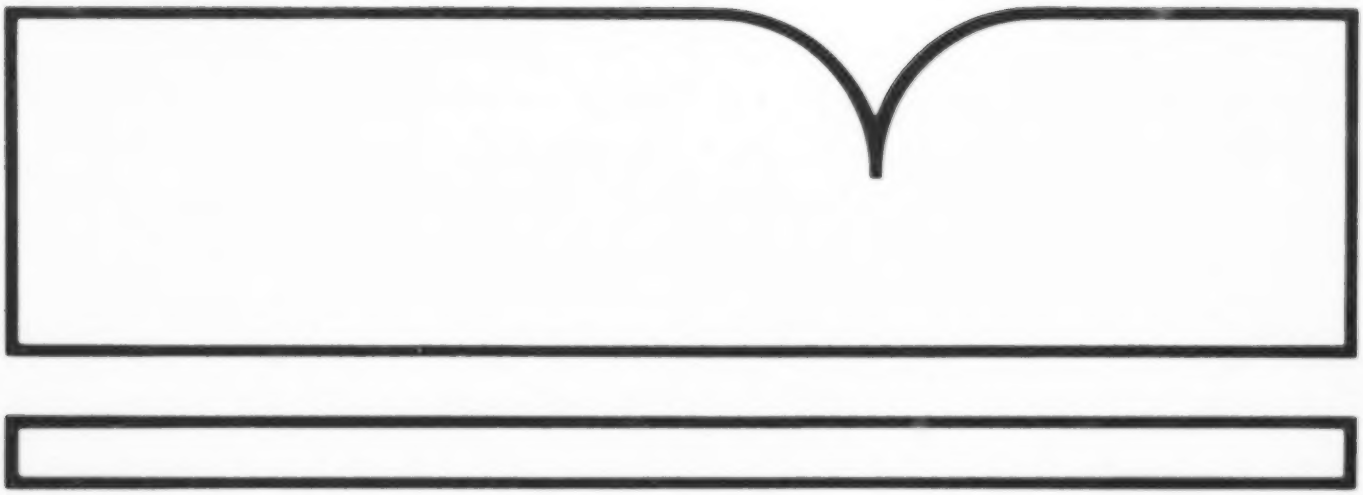

U.S. Department of Commerce
National Technical Information Service
NTIS

United States
Environmental Protection
Agency

Office of Pesticides and Toxic Substances
Office of Pesticide Programs (TS-766C)
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EPA

Pesticide Fact Sheet

Name of Chemical: Chlorothalonil
Reason for Issuance: Registration Standard
Date Issued: September 30, 1986
Fact Sheet Number: 36

1. Description of the chemical:

- Generic name: Tetrachloroisophthalonitrile
- Common name: chlorothalonil
- Trade name: Bravo®, Nopcocide® N-96, Daconil®, Chlorothalonil Technical Termil®, Groutcide®, Mold-Ex®, Bravomil®
- EPA Shaughnessy Code: 081901
- Chemical Abstracts Service (CAS) Registry number: 1897-45-6
- Year of initial registration: 1966
- Pesticide Type: Fungicide
- Chemical family: Chlorinated isophthalic acid derivative
- U.S. and foreign producers: SDS Biotech Corporation and Griffin Chemical Company

2. Use patterns and formulations:

- Application sites: chlorothalonil is a chlorinated isophthalic acid derivative registered for use as a fungicide to control a wide variety of fungal diseases on both crop and noncrop sites. Chlorothalonil is registered for use on numerous crop sites such as fruits, vegetables, and peanuts. In non-crop applications, chlorothalonil is used on ornamental sites, on turf, and as a paint and grout additive.
- Types of formulations: chlorothalonil is available in wettable powder, granular flowable, palleted/ tableted, liquid suspension, and soluble concentrate formulations.
- Types and methods of applications: chlorothalonil is applied as follows: broadcast, band, and soil surface using ground or aerial equipment.
- Application rates: 0.75 lbs. a.i./A to 3.0 lbs. a.i./A on crop sites; and 1.125 lbs. a.i./A to 7.5 lbs. a.i./A on non-crop sites.
- Usual carrier: Water.

3. Science Findings:

a. Summary of science findings:

- Chlorothalonil breaks down in aerobic soil with a half-life of 1 to 2 months with the formation of a major degradate, 4-hydroxy-2,5,6-trichloroisophthalonitrile, and several lesser degradates. This breakdown appears to be primarily the result of microbial degradation, since chlorothalonil is relatively stable to hydrolysis and photolysis. Chlorothalonil is immobile in most soil types, except sand in which it is moderately mobile. The 4-hydroxy degradate is moderately mobile in most soil types.

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15. Supplementary Notes

16. Abstract (Limit: 200 words)

This document contains up-to-date chemical information, including a summary of the Agency's regulatory position and rationale, on a specific pesticide or group of pesticides. A Fact Sheet is issued after one of the following actions has occurred.

1. Issuance or reissuance of a registration standard,
2. Issuance of each special review document,
3. Registration of a significantly changed use pattern,
4. Registration of a new chemical, or
5. An immediate need for information to resolve controversial issues relating to a specific chemical or use pattern.

17. Document Analysis a. Descriptors

Pesticides, regulations, Chemical Information Fact Sheet, Use Patterns, Science Findings

b. Identifiers/Open-Ended Terms

c. COSATI Field/Group

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(See ANSI-Z39.18) See Instructions on Reverse

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- Chlorothalonil is not toxic to birds. However, the major degradate is moderately toxic to birds. Additional studies are required for chlorothalonil and the 4-hydroxy degradate in order to determine whether residues of these compounds will produce an effect on the reproduction of birds.
- Chlorothalonil and its 4-hydroxy degradate are highly toxic to fish, aquatic invertebrates and marine/estuarine organisms. Low amounts of residues will affect the reproduction of these organisms. An additional field monitoring study is required that would record the effects of residues occurring in water resulting from registered uses of chlorothalonil.
- The metabolism of chlorothalonil in plants and animals is not adequately elucidated. However the major metbolite is the 4-hydroxy-2,5,6-trichloroisophthalonitrile. At low concentrations, chlorothalonil is expected to be excreted in the feces and urine within 24 hours. The amount of residues expected to be in or on raw agricultural commodities from use of chlorothalonil will be reassessed when the data on plant and animal metabolism are submitted along with the additional residue data.
- The impact of the manufacturing impurities of hexachlorobenzene and pentachlorobenzonitrile in chlorothalonil cannot be made until plant and animal residue data is submitted for this impurities.
- Chlorothalonil is a severe eye irritant. It is moderately toxic via inhalation and demonstrates low toxicity via dermal and oral exposures. Chlorothalonil is not considered to be mutagenic, teratogenic, or cause reproductive effects. Studies demonstrated that the chemical could have oncogenic potential, but additional data are needed to confirm this.
- The major metabolite is not considered to be an oncogen or mutagen.

b. Chemical characteristics:

- Technical chlorothalonil is an odorless or slightly pungent, white, crystalline solid. It is stable towards moisture under conventional conditions and decomposes at 250-251° Celsius. The chemical does not exhibit any unusual handling hazards. Technical chlorothalonil contains low amounts of hexachlorobenzene (HCB) and pentachlorobenzonitrile (PCBN) as manufacturing impurities.

c. Toxicological characteristics:

- Technical chlorothalonil is a severe eye irritant, moderately toxic via inhalation, and of low toxicity via oral and dermal exposures. The toxicity categories assigned to chlorothalonil are I for eye irritation, II for inhalation, III for oral and dermal toxicities, and IV for dermal irritation.
- Toxicology studies on chlorothalonil are as follows:

  - Oral LD_{50} in rats: > 28.2 mg/kg body weight,

  - Dermal LD_{50} in rat: >10 gm/kg body weight,

  - Skin irritation in rabbits: not an irritant

  - Eye irritation in rabbits: severe irritant

  - In a two-year rat chronic feeding study, the no-observed-effect-level was 60 ppm (3 mg/kg body weight). However, it was not adequate to address the evaluate oncogenic potential of chlorothalonil.

- In a two-year feeding study in dogs, the no-observed-effect-level was 60 ppm.

- In a 24-month mouse oncogenicity study, chlorothalonil produced tumors in renal cortical tubules and squamous tissue of the stomach, however there was no dose related response. The study demonstrates that chlorothalonil may have oncogenic potential. An additional two-year feeding study in rats is considered a data gap.

- In a three-generation rat reproduction study, the no-observed-effect-level for chlorothalonil is <0.15% of the diet based on reduced growth and renal and gastric effects. No teratogenic effects were observed at any dose level tested under the conditions of the study. Reproductive effects were observed at 0.15% of the diet.

- In a rabbit teratology study and rat teratology study utilizing chlorothalonil and a rat and a rabbit teratology study utilizing the 4-hydroxy metabolite, no significant teratogenic effects were observed at any dose levels tested under the conditions of the studies.

- Chlorothalonil did not demonstrate any mutagenic effects in a variety of mutagenicity tests.

- The 4-hydroxy metabolite is not oncogenic in rats at doses of 20.0 mg/kg body weight/day [Highest Dose Tested(HDT)] or less and in mice at doses of 215 mg/kg body weight/day (HDT) or less under the conditions of the study.

- The 4-hydroxy metabolite did not demonstrate any mutagenic effects in a variety of mutagenicity studies.

d. Physiological and Biochemical Behavioral Characteristics:

- Translocation: chlorothalonil is translocated in plants.
- Mechanism of pesticidal action: The mode of action of chlorothalonil involves its reaction with thiol groups of the pathogenic fungi's enzyme systems.
- Metabolism and persistence in plants and animals: The metabolism of chlorothalonil is not adequately delineated in both plants and animals. However, the major metabolite is the 4-hydroxy metabolite.

e. Environmental characteristics:

- The available environmental fate data are insufficient to fully assess the potential for exposure of humans and non-target organisms to chlorothalonil. When additional studies are submitted, a complete environmental exposure assessment can be made. However, chlorothalonil is moderately mobile in sand and the 4-hydroxy degradate is moderately mobile in most soils.

f. Ecological characteristics:

- Avian oral LD_{50}: chlorothalonil (>10,000 mg/kg) uses are not expected to affect avian wildlife. 4-hydroxy degradate (2000 mg/kg), is moderataly toxic to birds. Reproduction studies using both mallard ducks and bobwhite quail for each, chlorothalonil and the 4-hydroxy degradate, are required.
- LC_{50} to fish: chlorothalonil (47-84 ppb) is highly toxic to fish. the 4-hydroxy degradate (16-45 ppm) is slightly toxic to fish.
- Fish reproduction: Chlorothalonil may affect fish populations at low levels (3 - 6.5 ppb).
- LC_{50} aquatic invertabrates: Chlorothalonil is highly toxic to aquatic invertabrates and may affect their reproduction at low concentrations (>79 ppb).
- An aquatic field monitoring study is required that reflects residue concentrations likely to occur under actual use conditions.

g. Tolerance assessments:

- A reassessment of the tolerances cannot be completed at this time. The residue data on the amounts of impurities in or on the commodities, the rat oncogenicity/chronic feeding study, and metabolism data, need to be submitted and evaluated before any assessment of the present tolerances can be made.

4. Summary of regulatory position and rationale:

- No use, formulation, or geographical restrictions are required.
- Chlorothalonil will be provisionally regulated as an oncogen. This position is based on a study in which chlorothalonil has exhibited renal adenomas and carcinomas in male mice and somewhat flawed NCI studies that indicate an oncogenic effect in the rat, but not in mice. This position will be reconsidered after the review of the ongoing rat chronic feeding/oncogenicity study in 1985. As a result of this evaluation, chlorothalonil may be referred to a Special Review.
- Skin sensitization study is a data gap. However, information received through the Pesticide Incident Monitoring System indicates that skin sensitization is a potential problem.
- Unique labeling statements:
  Under "Hazards to Humans and Domestic Animals", the words "Skin Sensitizer" must be added.
  Under "First Aid", the following statement must be added: "Note to Physician: Persons having an allergic reaction respond to treatment with antihistamines or steroid creams and/or systemic steroids."
  Under "Environmental Hazards", the following must be used: "This product is toxic to fish, aquatic invertebrates, and marine/estaurine organisms."

Under "Directions for Use", the following statements must be added:
"Note to User: This product may produce temporary allergic side effects characterized by redness of the eyes, mild bronchial irritation and redness or rash on exposed skin areas. Person having allergic reaction should contact a physician."
"Note to User: Wear long sleeve shirt, long pants, and gloves when mixing, loading and applying this product.'
"Note to User: Do not enter treated area to perform hand labor within 24 hours of application unless protective clothing is worn."
"Note to User: Do not rotate to crops other than those listed on the label within one year from last application. Leafy vegetables may be rotated after one year from last application."

5. Summary of major data gaps:

a. The following toxicology data are required:

- An oncogenic study in rats (currently underway) is required to be submitted within one year.
- A skin sensitization study is required to be submitted within one year.
- A 21-day subchronic dermal study is required to be submitted within one year.

b. The following environmental fate data are required:

- Hydrolysis test, (2)
- Photodegradation test in water, (2)
- Photodegradation test on soil, (2)
- Photodegradation test in air, (2)
- Metabolism test in anaerobic soil, (1)
- Metabolism test in aerobic soil, (1)
- Leaching study (2)
- Mobility (volatility) test in the laboratory, (2)
- Mobility (volatility) test in the field, (2)
- Dissipation study in soil (1)

(1) Long-term studies must be submitted within 15 months after receipt of the guidance package. (2) Short-term studies must be submitted within six months after receipt of the guidance package.

c. The following ecological effects data are required:

- An field study is needed for the determine the effects of residues on fish and aquatic invertabrate occuring as a result of the terrestial use of chlorothalonil.
- Mallard duck and bobwhite quail reproduction study with chlorothalonil and with it 4-hydroxy degradate are needed.

These long-term studies must be submitted within 15 months after receipt of the guidance package.

d. The following residue chemistry data are required:

- Data related to the manufacturing process, formation of impurities, preliminary analysis of the technical product, certification of ingredient limits, analytical methodology, and physical/chemical characteristics. (2)
- Field residue data for several raw agricultural commodities.
- Studies pertaining to the metabolism of chlorothalonil residues in plants and animals. (1)
- Residues studies regarding the presence of hexachlorobenzene and pentachlorobenzonitrile in plants and in animals. (1)

(1) Long-term studies must be submitted within 15 months after receipt of the guidance package. (2) Short-term studies must be submitted within six months after receipt of the guidance package.

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